

EUnetHTA-EFPIA Technical Meeting

11 December 2018

12:30-18:30 CET

Haute Autorité de Santé, Paris

Meeting called by: EUnetHTA Executive Board
Facilitator: EUnetHTA Secretariat (WP1)
Haute Autorité de Santé

Type of meeting: Face-to-face meeting
Chair: Niklas Hedberg, EUnetHTA (TLV)
Ansgar Hebborn, EFPIA (Roche)

Attendees:
(EFPIA)
Salem Abi Nehme, Celgene
Sylvie Duclaux, Servier
Kalitsa Filioussi, Novartis
Edith Frénoy, EFPIA
Adrian Griffin, Johnson & Johnson
Oliver Günther, Merck KGaA
Ansgar Hebborn, Roche
Patrick Hopkinson, BMS
Gabriele Kapfer, Bayer
Stephanie Lane, MSD
Charlie Nicholls, Sanofi

Samantha Parker, Lysogene
Adam Parnaby, Celgene
Gesa Pellier, Novartis
Laurent Petit, Leem
Milena Richter, Sanofi
James Ryan, AZ
Tina Taube, VFA
Tom Vandebrouck, Novo Nordisk Region Europe
Aurelie Waeckel, Pfizer
Raphael Yugi, Takeda

Attendees:
(EUnetHTA)
Chantal Belorgey, HAS
Patrice Chalon, KCE
Nick Crabb, NICE
Anne d'Andon, HAS
Rudy Dupree, ZIN
Judith Fernandez, HAS
Maggie Galbraith, HAS
Zoe Garrett, NICE
Marcus Guardian, ZIN
Chantal Guilhaume, HAS
Irena Guzina, HAS

Niklas Hedberg, TLV
Ali Hussain, ZIN
Dominique Le Guludec, HAS
Pilar Martin Vivaldi, NOMA
Tuomas Oravilahti, FIMEA
Helen Powell, NICE
Ingvil Saterdal, NIPHNO
Bjørn Oddvar Strøm, NOMA
Giovanni Tafuri, ZIN
Beate Wieseler, IQWiG
Anne Willemsen, ZIN

Attendees:
(Other)
Michael Berntgen, EMA
Flora Giorgio, DG SANTE

Minutes

Agenda item #1: Welcome, introductions and adoption of the agenda

Presenter: Niklas Hedberg, EUnetHTA (TLV)
Ansgar Hebborn, EFPIA (Roche)

Discussion:

The chairs welcome participants to the meeting and thank everyone for their time. This is followed by a short introduction by each participant.

Conclusions:

The agenda is adopted without changes.

Agenda item #2: Governance changes in EUnetHTA

Presenter: Niklas Hedberg, EUnetHTA (TLV)

Discussion:

EUnetHTA briefly presents a summary of governance changes in the project.

A new risk register has been created to log potential challenges and issues in real-time. A new chair of the Executive Board has also been elected (Niklas Hedberg, TLV) as well as two vice-chairs (Chantal Belorgey, HAS and Zoe Garrett, NICE). The function and role of the Executive Board was clarified in the process and part of this meant realigning task groups to fall under the Board's oversight. The Board also now meets more frequently with more face time, providing greater opportunities for discussion and reflection.

Work has also begun on the future model of collaboration on HTA (WP1 deliverable). The model will take into consideration achievements of current and former Joint Actions as well as the legislative proposal on European HTA framework currently under discussion before Parliament and Council.

NIPHNO briefly recaps the structural changes in Work Package 4. This includes the addition of the Norwegian Medicine Agency (NOMA) as an additional co-lead partner, who will be jointly responsible for Joint Assessments.

Conclusions:

Participants acknowledge the update on the state of governance in EUnetHTA.

Agenda item #3: Joint Production and National Implementation
Part one

Moderators: Edith Frénoy, EFPIA
Giovanni Tafuri, ZIN

Discussion:

- a) Experience of REAs – Improvement of the process and submission requirements | Rudy Dupree and Anne Willemsen, ZIN

ZIN describes the improvements to the process resulting from the interactions with manufacturers and the lessons learned from the experience with REAs. The improvements are related to different stages of the process covering the scoping phase, submission requirements, templates and stakeholder engagement. The scoping face to face meeting also now focuses more on the PICO.

ZIN clarifies the process regarding the selection of authors and co-authors. Particular attention is paid to those partners who can indicate re-use.

EFPIA relay that it was positive to see scoping is now focusing on PICO. The scoping face to face meeting is roughly two to three months before CHMP opinion. Some discussion followed on the resolution of potential differences regarding the uptake of the PICO at a national level. EUnetHTA indicated that resolution of potential differences can encompass discussion within the assessment team, with the coordination team and ultimately with intervention of the senior scientific officer.

General agreement that discussing implementation and re-use early on in the assessment is a positive step forward.

Sanofi recommends greater definition of the scoping process. Communication with the company, around the time when the assessment is due to be made public, is important and must be encouraged.

Based on earlier discussions, EUnetHTA no longer requires a draft submission file but requires a scoping document. At the same time, EUnetHTA created a more comprehensive Letter of Intent. It was raised that the current Letter of Intent could serve as the scoping document to inform the team for the scoping F2F meeting.

b) Use of reports at a national level | Nick Crabb, NICE

A general discussion on criteria to define implementation took place. Regarding Midostaurin, there is agreement that Information from country colleagues correlates with EUnetHTA findings.

J&J emphasise the need for a common definition of categories of reuse, to ensure alignment between all stakeholder on interpretation of uptake.

c) Brief update on the EUnetHTA Prioritisation List (EPL) | Rudy Dupree and Anne Willemsen, ZIN

ZIN provides a brief update on the status of the EUnetHTA Prioritisation List. It is stressed that this is an ad-hoc activity aimed at producing assessments with high uptake rates and to increase production. Voluntary submissions are welcomed and continue to be the central method of obtaining products for Joint Assessments.

d) Topic Identification, Selection and Prioritisation (TISP) – Update | Ingvil Saterdal, NIPHNO

A brief exchange was held on the topic, with questions relating to the procedure taken up by NIPHNO.

Conclusions:

a) Experience of REAs – Submission requirements | Rudy Dupree and Anne Willemsen, ZIN

A thorough description of the submission dossier (core submission dossier and appendices) is provided by ZIN. ZIN stressed that the submission dossier is to be shared with the entire assessment team, and that the authoring team is free to cite from the submission dossier in the Joint Assessment report.

To facilitate national implementation, the core submission dossier is to be made public at time of the publication of the final Joint Assessment report. It was clarified that appendices to the submission dossier, such as Clinical Study Reports, can be cited in the Joint Assessment reports but will not be made public by EUnetHTA.

b) Experience of REAs – Process of assessment | Rudy Dupree and Anne Willemsen, ZIN

WP4 pharma will critically look at the current template for the scoping document and the Letter of Intent template to reduce duplication of work.

To strengthen national impact of the Joint Assessment reports, WP4 is looking into whether it is feasible to publish reports closer to the EC decision (official market authorisation). EFPIA will look into technical details, such as if the company can share the draft EPAR.

c) Use of reports at a national level | Nick Crabb, NICE

Agreement that the continuation of WP7 work on implementation is key. A focus on non-duplication of joint work is essential from an Industry perspective.

Agreement that greater clarity on the definition of use is needed urgently in order to converge understandings.

Agreement that mapping use and what it looks like from both perspectives would be useful and should be explored.

d) Brief update on the EUnetHTA Prioritisation List (EPL) | Rudy Dupree and Anne Willemsen, ZIN

The update was welcomed by both sides. EFPIA underlined that for a future system of prioritisation to be robust, it must ensure iterative engagement with industry, starting early in the process and including a validation step before publication. The first EUnetHTA prioritisation list included factual mistakes which could have been avoided by fact-checking with companies.

e) Topic Identification, Selection and Prioritisation (TISP) – Update | Ingvil Saterdal, NIPHNO

The update was welcomed by both sides.

Action items	Person responsible	Deadline
✓ Explore earlier publication of Joint Assessment reports	EFPIA and EUnetHTA WP4	Q4 2019
✓ Define and send through constructive input on the scoping document	EFPIA	Q4 2019
✓ Implementation survey for companies' experience in mapping of use	EUnetHTA (NICE)-EFPIA	Project initiated findings to be included in May 2019 implementation report

Agenda item #4 Guidelines and SOPs
Part two

Presenter: Various

Discussion:

a) SOPs – An update | Beate Wieseler, IQWiG

A brief update on the areas in which SOPs are being created for EUnetHTA is presented.

b) Methodological Guidelines – An update | Patrice Chalon, KCE

An update on the guideline production process is provided. It is highlighted that 15 guidelines have been published, two are under revision and a further two are under development. The completed guidelines are available to read on the EUnetHTA website. EUnetHTA continue to welcome any comments, suggestions and inputs on the methodological guidelines.

EFPIA underlined the need to engage the stakeholder community, including industry, in discussing and commenting on methodological guidelines, beyond public consultations (eg workshops), in line with prior experience at both EMA and national HTA level but also within EUnetHTA JA2. EFPIA expressed the need to, *de minimis*, set up a face-to-face meeting to discuss questions on comments and suggestions raised within the public consultation, in line with practice at national level (eg Germany).

Conclusions:

a) SOPS – An update | Beate Wieseler, IQWiG

The update was welcomed and acknowledged.

b) Methodological Guidelines – An update | Patrice Chalon, KCE

The update was welcomed and acknowledged.

Action items

Person responsible

Deadline

- ✓ IQWiG and KCE to follow up on updates on methodological guidelines
- ✓ EUnetHTA to consider how to best respond to the EFPIA request for discussing comments expressed on guidelines.

IQWiG

Q4 2019

Agenda item #4 Evidence Generation

Presenter: Various

Discussion:

a) Experience on Early Dialogues | Maggie Galbraith, HAS

An update is provided on Early Dialogues and the Parallel Consultation process. HAS highlight that a survey was sent out to Industry participants following each ED procedure, the results of which are available in the accompanying slide deck. Further details can be requested with HAS.

b) Update on Post Launch Evidence Generation (PLEG) projects | Irena Guzina, HAS

An update is provided on EUnetHTA work surrounding PLEG projects. EUnetHTA confirms it would be happy to welcome initiations for pilots from Industry.

Conclusions:

a) Experience on Early Dialogues | Maggie Galbraith, HAS

The sharing of experience was welcomed and acknowledged.

b) Update on Post Launch Evidence Generation (PLEG) projects | Irena Guzina, HAS

There is general agreement that the Parallel Consultation process has been very useful for companies and that work must continue on this.

Specific questions in the ED survey were discussed, EFPIA representatives suggested rewording some of them to avoid potential misunderstandings.

Action items

Person responsible

Deadline

- ✓ HAS to reconsider the wording of specific questions in the ED survey

HAS

Q4 2019

Agenda item #5 Update from DG SANTE, European Commission

Presenter: Flora Giorgio, DG SANTE

Discussion:

DG SANTE provided an update on the EU HTA proposal. The Commission recapped the key articles of the proposal and presented the current state of play within the EU institutions.

It is noted that on the 3rd of October 2018, the European Parliament adopted, by a very comfortable majority, its report on the amendments. Overall, the European Parliament supports the Commission's approach. The amendments aim to further detail how the system of EU-level cooperation should work while largely remaining consistent with the original objectives of the proposal.

Within the Council, the Austrian presidency has presented a progress report to EPSCO; the first meeting of the Romanian presidency, will be held on the 8th of January 2019, and an official meeting is scheduled to take place every three weeks.

Conclusions:

The update is acknowledged by attendees.

Agenda item #6 European Medicines Agency: Update on EMA-EUnetHTA collaboration **Presenter:** Michael Berntgen, EMA

Discussion:

An update on the EMA-EUnetHTA work plan is provided. The update focused on the ongoing activities on Early Dialogues, post-licensing evidence generation, collaboration at time of market access and patient engagement.

Conclusions:

The update is acknowledged by attendees.

Agenda item #7 Closing remarks from President of HAS **Presenter:** Dominique Le Guludec, HAS

Discussion:

President of HAS, Dominique de Guludec welcomes attendees to HAS. The President noted that collaboration between EUnetHTA and EFPIA is vital and meetings such as these are positive indicators of what can be achieved through proactive dialogue.

Conclusions:

Attendees welcome the remarks and thank HAS for hosting the meeting.

Agenda item #8 Closing remarks and summary of actions and decisions **Presenter:** Niklas Hedberg, EUnetHTA (TLV)
Ansgar Hebborn, EFPIA (Roche)

Discussion:

EUnetHTA thanks EFPIA and their members for attending the meeting and summarises noted action points. The discussions were not only useful but provide a framework for further collaborative steps.

Conclusions:

Agreement that the annual technical meeting is a useful arena for feedback and should continue.